

REMARKS

Reconsideration of this application is respectfully requested.

Claim 23 has been rewritten to depend from claim 22. Claims 45-47 have been amended to recite the specific form of *Mycobacterium w* present in the composition. Claim 49-54 have been added. New claim 49 recites a method of treating obstructive lung disease by administering to a patient a pharmaceutical composition comprising an effective amount of (a) heat killed whole cell *Mycobacterium w*, (b) sonicated *Mycobacterium w*, (c) a solvent extract of *Mycobacterium w* (where the solvent is selected from chloroform, ethanol, methanol, and acetone), or (d) an enzymatic extraction of *Mycobacterium w* (where the enzyme is liticase). Support for these amendments is found in the specification at, e.g., pages 5-8, 11, and 12. No new matter has been added by way of this amendment.

Claims 22-29, 32, 34, 36-43, and 45-54 are pending. Because claim 48 has been allowed, only claims 22-29, 32, 34, 36-43, 45-47, and 49-54 are at issue.

Enablement Rejection

Claims 22-27, 32, 34, and 36-43 have been rejected as lacking enablement. The Examiner concedes that the specification provides support for compositions comprising heat killed whole cell *Mycobacterium w*, sonicated *Mycobacterium w*, *Mycobacterium w* enzyme extracts isolated from liticase, and solvent extracts of *Mycobacterium w* prepared from chloroform, ethanol, methanol, and acetone. (Applicants respectfully point out that the compositions that the Examiner has conceded are properly supported by the specification are recited in new claims 49-54.) The Examiner,

however, contends that the application lacks enablement for solvent and enzymatic extracts that are not recited in the working examples.

The rejection is traversed, and reconsideration is respectfully requested.

Applicants respectfully submit that one of ordinary skill in the art could prepare solvent extracts of *Mycobacterium w* with any of the solvents recited in claim 22 without undue experimentation. The specification specifically teaches that the solvent extraction can be performed using organic solvents such as chloroform, ethanol, methanol, acetone, phenol, isopropyl alcohol, acetic acid, urea, or hexane. *See* specification at, e.g., page 11. The specification further describes exemplary compositions of solvent extracts prepared with 1×10^{10} *Mycobacterium w* cells treated with either methanol, chloroform, acetone or ethanol. *See* specification at, e.g., pages 6 and 7.

Pursuant to MPEP §2164.04, “[i]n order to make a rejection, the examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention.” Furthermore,

A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.

Id.

Here, there is no reason to doubt the objective truth of the statements contained in the specification regarding the use of solvent and enzyme extracts other than those exemplified. For instance, one of ordinary skill in the art would readily appreciate that solvent extracts could be prepared with alcohols specifically recited in the specification (i.e., isopropyl alcohol and phenol) in addition to those exemplified (i.e., methanol and ethanol).

With respect to the enzyme extracts of *Mycobacterium w*, the specification discloses that the enzymatic extraction can be performed using proteolytic enzymes which digest cellular walls or membranes. Litcase and pronase are known in the art as proteolytic enzymes, and are both disclosed in the specification as preferred enzymes for the *Mycobacterium w* enzymatic extraction. See specification at, e.g., page 12. The specification further discloses an exemplary composition comprising a litcase extract of 1×10^{10} *Mycobacterium w* cells. See specification at, e.g., page 7. Accordingly, the original specification provides sufficient guidance which would enable one of ordinary skill in the art to prepare a *Mycobacterium w* extract using pronase as the proteolytic enzyme.

Finally, the Examiner has failed to explain why he doubts the accuracy of the statements in the specification. MPEP §2164.04 ("it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement." (quoting *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971)).

In view of the foregoing, applicants respectfully submit that the presently claimed methods are enabled. Accordingly, applicants respectfully request that this rejection be withdrawn.

Indefiniteness Rejection

Claims 45, 46, and 47 have been rejected as indefinite for failing to recite the specific form of *Mycobacterium w*. In response, and without conceding the validity of the rejection, claims 45-47 have been amended to include the form of *Mycobacterium w* present in the composition. Thus claims 45-47 are definite and applicants respectfully request that this rejection be withdrawn.

Claims 28 and 29 have been rejected as indefinite for depending from a rejected claim (i.e., claim 22). Applicants respectfully submit that, in view of the arguments and amendments set forth above, claim 22 is allowable. Accordingly, claims 28 and 29, which depend from claim 22, are also allowable. Withdrawal of this indefiniteness rejection is respectfully requested.

CONCLUSION

In view of the above amendments and remarks, it is respectfully requested that the application be reconsidered, and that the pending claims be allowed and the case passed to issue.

If there are any other issues remaining that the Examiner believes can be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

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Respectfully submitted,

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